REMARKS

Applicants have presently amended claims 8, 46-49, 60, and 66. The support for these amendments can be found in the specification at, for example, page 8, line 12; page 9, lines 3-6 and lines 19-22; page 10, lines 8-18; and the claims as originally filed. Newly presented claims 76-81 have also been added. The support for new claims 76-78 can be found in the specification at, for example, page 9, lines 19-22, and the claims as originally filed. The support for new claims 79 and 80 can be found in the specification at, for example, page 8, line 12; and page 9, lines 3-6; and the claims as originally filed. The support for new claim 81 can be found in the specification at, for example, page 10, lines 25-27, and the claims as originally filed.

After entry of the current amendment, claims 8-14, 46-53, 59, 60, 66-72, and 76-81 will be pending.

The Office action has also stated that the subject matter of claim 72 is allowable.

Enclosed is a check in the amount of $394.00 that includes a fee of $284.00 for the additional claims plus a fee of $110.00 for the One-Month Extension of Time. It is believed that no additional fee is due. However, if any fee is due, please charge Kagan Binder Deposit Account No. 50-1775 and notify us of the same.

Claim Rejections - 35 U.S.C. § 103

The Office action has rejected claims 8-14, 46-53, 59, 60, 66-71 under 35 U.S.C. 103(a) as being unpatentable over Cooper et al. (U.S. Patent No. 5,641,501; herein referred to as "Cooper") in view of Stinson (U.S. Patent No. 6,245,103; herein referred to as "Stinson") and Kaplan et al. (U.S. Patent No. 5,320,624; herein referred to as "Kaplan").

Applicants have amended claim 46 which now recites:

A bioresorbable, self-expanding stent comprising a tubular-shaped bioresorbable member having first and second ends, said bioresorbable member **consisting essentially of a blend of two bioresorbable, bio-compatible homopolymers**, the stent having a non-compressed diameter of between approximately 12 millimeters and 18 millimeters.

Applicants believe that this amendment overcomes the obviousness rejection based on the cited references. The cited references taken individually or in combination do not specifically teach a stent **consisting essentially of a blend of two bioresorbable, bio-compatible homopolymers** as recited in the presently amended claims, and are further not believed to suggest or provide any motivation for making such a stent as claimed.

Cooper

Cooper is cited as the primary reference and generically teaches the use of absorbable biocompatible polymer blends to manufacture medical devices. It is noted that Cooper is not specifically directed to stents.

Cooper teaches binary (blend of two polymers) and tertiary (blend of three polymers) absorbable, biocompatible, polymer blends (column 4, line 37 to column 5, line 13). All of the binary blends that are described by Cooper include a copolymer, typically poly(ε-caprolactone-co-p-dioxanone). The tertiary blends that are described by Cooper have three polymers, which can be homopolymers or combinations of homopolymers and copolymers.

However, Cooper does not describe a stent consisting essentially of two bioresorbable, bio-compatible homopolymers, as recited in the Applicants' amended claims. Furthermore, Cooper is not seen to suggest, or provide any motivation for, using a binary blend consisting essentially of two bioresorbable, bio-compatible homopolymers.

Applicants' invention is specifically directed to the preparation of bioabsorbable biocompatible stents having stable and predictable physical characteristics (see page 4, lines 16-25). As discussed in the Applicants' background, the prior art teaches use of bioabsorbable stents constructed from copolymers, but these stents are susceptible to hydrolytic decomposition and also inconsistencies, due to batch-to-batch variations in copolymer preparation. Therefore, some objectives of Applicants' invention are to provide improved resistance to hydrolytic decomposition and improved overall consistency in stent preparation.

Indeed, these objectives have been met by the Applicants' inventive stent constructions that consist essentially of a blend of two bioresorbable, bio-compatible

homopolymers as recited in the presently amended claims. The improvements with regard to the claimed stents are discussed on page 10, lines 8-18, and clearly demonstrate that the blend of two homopolymers results in increased resistance to hydrolytic attack, further providing improved physical and biological properties to the stent.

The challenge that is solved in the Applicants' claimed invention is not appreciated by Cooper. For example, Cooper is silent with regard to how particular polymer blends affect the susceptibility to hydrolytic attack on the formed medical device or how the blends affect the batch-to-batch consistency of stent preparations. Rather, Cooper is believed to direct its reader to the use of biodegradable copolymers because they are thought to improve mechanical aspects of medical devices, such as stiffness and breaking shape retention.

Cooper states that his objective is to generate "novel polymer mixtures which have improved dimensional stability, shape retention, and palpability, while retaining the excellent strength, stiffness and breaking strength retention (BSR)..." (column 1, lines 58-61). To achieve this goal, Cooper suggests that it would be, "highly desirable to develop blends which were not dependent upon large additions of a ductile polymer to create bendability in the fixation device, but were dependent upon smaller additions of a low melting polymer..." (column 2, lines 16-20; emphasis by Applicant).

This goal of Cooper is clearly seen to be achieved by including a copolymer in an absorbable biocompatible polymer blend as described in column 11, lines 15-25: "For example, as found for the binary blends of this invention, by the addition of small amount of a poly(ε-caprolactone-co-p-dioxanone) copolymer to a poly(lactide-coglycolide) copolymer, better shape retention can be obtained. That is, by heating the plate to 80°-120°C to bend it to the shape of the fractured bone, the poly(ε-caprolactone-co-p-dioxanone) copolymer will melt, causing the plate to "flow" and bend more easily. Once the plate has cooled, the poly(ε-caprolactone-co-p-dioxanone) copolymer crystalizes, "locking" the newly contoured shape into the plate."

The importance of using a copolymer for the construction of medical articles is clearly reflected in Examples 1-8 of Cooper wherein it is noted that either poly(lactide-co-glycolide) or poly(ε-caprolactone-co-p-dioxanone) are present in all of the binary and tertiary polymer blends.

The overall teaching of Cooper clearly emphasizes using a copolymer for improving material aspects of a biodegradable device. This overall teaching would contradict the position that Cooper provides any motivation for using a polymeric blend that does not include a copolymer for stent preparation, e.g., a blend consisting essentially of two homopolymers as recited in the Applicants' claims.

With regard to the use of polymer blends in the preparation of medical devices, the Office action has characterized Cooper as, "more specifically directed to the general use for the polymer blends." In fact, Cooper teaches that its polymeric blends are preferably used in particular medical devices. The preferred devices of Cooper are, "especially wound closure devices such as suture anchors, surgical staples, clips, sutures, plates and screws, comprising the above polymer blends," (emphasis by Applicants) as described in column 2, lines 43-46. See also Figures 2-4 of Cooper, which include illustrations of devices that have screws.

Cooper recites "stents" only in an extensive list of medical devices (column 5, line 63, to column 6, line 26). Although the Office action has stated, "stents along with other medical devices including fasteners, staples, clips, pin screws and the like have been fabricated from homopolymer blends as taught by Cooper," Applicants believe this statement is inaccurate. Despite the general reference to "stents" at column 6, line 25, the only device that was actually manufactured using the polymer blends as described by Cooper was a flex bar (Example 8). None of Examples 1-9 describe an actual construction of a stent using the polymer blends of Cooper.

The Office action also states that, "if not inherent in Cooper, et al., to fabricate a stent from the blend of homopolymers and ratios as taught by Kaplan would have been obvious to one with ordinary skill in the are based on manufacturing and surgical considerations." These entirely non-specific "manufacturing and surgical considerations," are again stated by the Office action without any explanation of what these considerations are, where these considerations come from, and how they apply in relation to the stent as claimed by the Applicants.

These points regarding the teaching of the medical devices of Cooper are presented (notwithstanding the Applicants' position that the claims as presently amended would not have been obvious over Cooper and the cited references) because the Applicants believe that the Office action has failed to present any persuasive argument as

to why a reader of Cooper would be inclined to choose a stent among the diverse list of medical devices recited, particularly in view of teachings that exemplify the use of polymeric blends for the preparation of wound closure devices.

Finally, it is noted that Cooper fails to teach various features of the stent as claimed, in particular, the features of the stent being self expanding, having a compressed diameter of between approximately 12-18 mm, and having a walled surface formed from a plurality of woven monofilaments.

Kaplan

In the current Office action Kaplan is cited as a secondary reference, and according to the Office Action, is said to disclose the use of a blend of homopolymers in the fabrication of surgical devices. However, with regard to surgical devices, Applicants have previously established that Kaplan neither teaches a stent nor provides any motivation for using specific blends of biodegradable polymers for the fabrication of prosthetic devices, such as stents. The current and previous Office actions have also acknowledged that Kaplan fails to disclose "a stent." The argument in the previous Office action that perhaps it would have been "inherent" in Kaplan to fabricate a stent or obvious to do so, "based on manufacturing and surgical considerations from the teachings of Stinson," has been abandoned in the current Office action.

Despite these admissions, the current Office action has now stated that, "Clearly the list of Kaplan would include "like" medical devices including stents as disclosed by Cooper." Applicants view this statement as unwarranted, and consistent with previously unsuccessful attempts at characterizing the teaching of Kaplan beyond its actual description. The devices that are described by Kaplan share no structural or functional similarity to that of a stent, or any sort of prosthetic device. Kaplan's description of medical articles, "such as staples, clips and the like and other implant devices, such as pins, and bone screws..." are considered fasteners and are clearly different than, and serve a different function than that of a stent. These types of devices do not specifically suggest stents, and are not asserted to suggest stents according to the rejection. The Cooper and Kaplan patents are independent of one another, and any assumption that the teaching of medical devices that are contemplated by Cooper is transposable to the teaching of Kaplan is completely unsubstantiated.

Furthermore, with regard to polymer blends, Kaplan fails to appreciate the challenge that is solved in the Applicants' claimed invention (as described), and in this way suffers from the same shortcomings as Cooper. Kaplan states that it is desirable to provide absorbable surgical devices having improved mechanical properties (column 3, lines 4-6), but does not address issues overcome by the Applicants' claimed invention, such as susceptibility to hydrolytic decomposition and batch-to-batch variations in copolymer preparation.

Similar to Cooper, Kaplan is believed to direct its reader to the use of biodegradable copolymers. Kaplan teaches, "In particularly useful embodiments, the compositions comprise a blend of a) a glycolide/lactide copolymer and b) a lactide/trimethylene carbonate copolymer" (see column 3, lines 27-33). This preferred teaching is reflected in the fact that all of the examples of Kaplan recite use of polymer blends that includes a glycolide/lactide copolymer. Again, similar to Cooper, this teaching of Kaplan would apparently contradict the position that Kaplan provides any motivation for using a polymeric blend that does not include a copolymer for stent construction, e.g., a blend consisting essentially of two homopolymers as recited in the Applicants' claims.

Overall, Kaplan does not disclose a stent, and the Office action has not convincingly demonstrated that there a suggestion or a motivation to combine the teaching of Kaplan with either that of Cooper or Stinson reference, to result in a stent as described in the presently amended claims.

Stinson

Stinson is directed to self-expanding stents made from biodegradable polymers (see abstract). The exemplary embodiments detailed by Stinson (Examples 1-17) detail PLLA and stents constructed from PLLA fibers. Column 19, line 3, states that PLLA is the most preferred absorbable polymer. Other prophetic examples are described (Examples 18-32).

Stinson, though, does not describe or suggest the preparation of a stent consisting essentially of a blend of two bioresorbable, bio-compatible homopolymers as recited in the presently amended claims. In this regard Stinson does not cure the deficiencies of Cooper or Kaplan.

New claims 76-78

Applicants believe that the teachings of the cited references do not describe a stent that includes a blend of two bioresorbable, bio-compatible homopolymers present in a ratio of between approximately 50:50 and 70:30. Applicants believe that these claims are patentable over the cited prior art, and respectfully request notification of its allowability, along with the other pending claims.

New claims 79-80

Applicants believe that the teachings of the cited references do not describe a stent that specifically includes poly-L-lactide and poly-ε-caprolactone homopolymers. Applicants believe that these claims are patentable over the cited prior art, and respectfully request notification of its allowability, along with the other pending claims.

New claim 81

Applicants believe that the teachings of the cited references do not describe a stent that specifically includes a blend of at least two homopolymers, wherein one of the homopolymers is poly-ε-caprolactone homopolymer having a molecular weight of 200,000 daltons or greater. Applicants believe that this is patentable over the cited prior art, and respectfully request notification of its allowability, along with the other pending claims.

Conclusion

For at least the reasons that have been described above, Applicants believe the claims, as presently amended, would not have been obvious in view of the cited references. In view of the amendments and remarks provided herein, Applicants believe that the all of the pending claims are in condition for allowance, and respectfully request notification thereof.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

Dated: 16 Nov 04

By: _____

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